

REMARKS

Claims 94-106 were pending in this application and claims 94 and 106 are cancelled by amendment herewith without prejudice to the filing of any related continuation, continuation-in-part or divisional application. New claim 107 has been added to more particularly point out subject matter that Applicants regard as their invention. Accordingly, claims 95-105 and 107 are pending.

Applicants thank the PTO for acknowledging that claim 104 as presently recited is allowable. With regard to the other claims, reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested. Claims 95-100 and 102-103 have been amended solely to correct their dependencies in view of the cancelled subject matter, and claims 101 and 105 have been amended to more particularly point out subject matter that Applicants regard as their invention. Support for the amendments may be found in the specification, for example, at page 4, lines 6-7 and 9-10; page 5, lines 26-28; page 6, lines 9-15; page 13, lines 16-20; page 20, line 22 through page 21, line 7; page 22, lines 7-14; page 27, lines 12-18; page 34, line 15 through page 35, line 17; page 36, lines 1-7; page 45, lines 6-27; and page 47, line 20 through page 48, line 6. Support for the newly added claim may be found in the specification, for example, at page 36, lines 1-7; page 45, lines 6-18; and page 45, line 26 through page 46, line 4. No new matter has been added.

REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The PTO rejects claims 94-100, 102-103, and 105 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The PTO concedes that the specification is enabling for an antibody or fragment thereof that specifically binds to a polypeptide having the sequence set forth in SEQ ID NO:2, 6, 10, 12, 14, or 16. The Action alleges, however, that the specification is not enabling for an antibody or fragment thereof that specifically binds to a polypeptide encoded by a polynucleotide that hybridizes to SEQ ID NO:1, 5, 9, 11, 13, or 15, or that comprises a

nucleotide sequence at least 90% identical to SEQ ID NO:1 5, 9, 11, 13, or 15, and that the scope of the claims is not commensurate with the scope of the disclosure.

The PTO also rejects claim 106 under 35 U.S.C. § 112, first paragraph, alleging that the claim is directed to subject matter that is not adequately described in the specification. More specifically, the PTO asserts that the specification does not support an antibody that specifically binds to a polypeptide encoded by a polynucleotide comprising a sequence at least 90% identical to SEQ ID NO:1 5, 9, 11, 13, or 15 or by a polynucleotide that hybridizes under stringent conditions to SEQ ID NO:1 5, 9, 11, 13, or 15, wherein the antibody also binds to naturally occurring BMP-5 or BMP-6.

Applicants respectfully traverse these grounds for rejection and submit that the instant application satisfies all requirements of 35 U.S.C. §112. The rejection of claim 106 is rendered moot by cancellation, without prejudice, of that claim according to the present amendment.

As disclosed in the specification and recited in the claims, the present invention relates in pertinent part to an isolated antibody or binding fragment thereof which binds to a TGF-beta binding protein, wherein said binding protein is selected from (a) a polypeptide encoded by a polynucleotide that comprises a nucleotide sequence selected from SEQ ID NOs:1, 5, 9, 11, 13, and 15, or a complementary sequence thereto, and (b) a polypeptide that comprises an amino acid sequence selected from SEQ ID NOs: 2, 6, 10, 12, 14, and 16. Accordingly, and in view of the amendment submitted herewith, where (i) the PTO concedes that the specification is enabling for an antibody or fragment thereof that specifically binds to a polypeptide having the sequence set forth in SEQ ID NO:2, 6, 10, 12, 14, or 16, as noted above, and where (ii) the application clearly teaches that such polypeptides may be encoded, respectively, by SEQ ID NOs:1, 5, 9, 11, 13, and 15 (*e.g.*, specification at page 5, lines 26-28), Applicants submit that there can be no lack of enablement for the claimed invention.

Applicants therefore respectfully submit that the rejections under 35 U.S.C. §112 have been obviated, and thus request that they be withdrawn.

REJECTIONS UNDER 35 U.S.C. §102

The PTO rejects claim 101 under 35 U.S.C. § 102(b), asserting that U.S. Patent No. 5,453,492 (“the ‘492 patent”) anticipates the subject matter of the claim. In particular, the Action alleges that claim 101 is “not limited to the sequences but only to the named protein, TGF-beta binding protein” and that the cited patent “teaches methods of making monoclonal antibodies to TGF-beta binding protein.”

Applicants respectfully traverse this rejection. The present invention is directed to a method of producing monoclonal antibodies, comprising (a) immunizing an animal with a TGF-beta binding protein or portion thereof, wherein said binding protein is selected from (i) a polypeptide encoded by a polynucleotide that comprises a nucleotide sequence selected from SEQ ID NOs:1, 5, 9, 11, 13, and 15, or a complementary sequence thereto, and (ii) a polypeptide that comprises an amino acid sequence selected from SEQ ID NOs: 2, 6, 10, 12, 14, and 16; (b) harvesting spleen cells from said animal; (c) fusing said spleen cells with a myeloma cell line; and (d) culturing said fused cells under conditions that allow the production of said antibody.

It is axiomatic that for a cited reference to anticipate a claimed invention, each and every limitation of the claim must be present in a single reference. For reasons also previously made of record, the PTO has failed to demonstrate that the ‘492 patent teaches each and every limitation of the presently claimed invention, and in particular, the ‘492 patent fails in any way to teach or suggest the presently claimed method employing the presently recited polypeptide sequences or polypeptide-encoding sequences. Therefore, no *prima facie* case of anticipation under 35 U.S.C. § 102(b) has been established. Applicants therefore respectfully request that the rejection be withdrawn.

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Reply to Office Action dated April 8, 2003

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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